

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-2043V

UNPUBLISHED

DEBORAH BELKER-FRECHETTE,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 6, 2023

Special Processing Unit (SPU);
Findings of Fact; Site of Vaccination
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

Sarah Black Rifkin, U.S. Department of Justice, Washington, DC, for Respondent

FINDINGS OF FACT¹

On October 19, 2021, Deborah Belker-Frechette filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), a defined Table injury, which was causally related to the influenza (“flu”) vaccine she received on October 5, 2020. Petition at 1, ¶¶ 3, 16.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

A fact dispute has arisen between the parties regarding the situs of vaccine administration. For the reasons discussed below, I find the flu vaccine was most likely administered in Petitioner's left deltoid, as alleged.

I. Relevant Procedural History

The day after filing the Petition, Ms. Belker-Frechette filed a signed declaration³ and some of the medical records usually required under the Vaccine Act. Exhibits 1-4, filed Oct. 20, 2021, ECF No. 6; see Section 11(c). Approximately four months later - on February 28, 2022, Petitioner filed the remainder of her required medical records. Exhibits 5-9, ECF No. 10. On March 2, 2022, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims). ECF No. 13.

After noting that the vaccine record did not indicate the site of administration, and identifying another potential roadblock to entitlement (evidence of prior left shoulder pain), I ordered Petitioner to file additional evidence and briefing. ECF No. 16. In response, Petitioner filed a supplemental signed declaration, statements from two friends,⁴ and a motion requesting that I issue a factual ruling finding the vaccine alleged as causal was administered in her left arm. Exhibits 10-12, ECF No. 18; Petitioner's Motion for Finding of Fact ("Motion"), ECF No. 19.

Emphasizing the lack of any information regarding the site of vaccination, along with her consistent reports of left shoulder pain post-vaccination (Motion at 10-11), Petitioner insists she "has preponderantly shown that she received the influenza vaccine in her left arm on October 5, 2020" (*id.* at 13). She also points to the information contained in the supporting statement from her friends as further evidence supporting her assertions. *Id.* at 11-13.

In reaction, Respondent argues that "there is currently no medical evidence to suggest that [P]etitioner was vaccinated in her left shoulder, beyond [P]etitioner's own statements to treating physicians." Respondent's Response and Status Report, filed Sept. 13, 2022, at 2, ECF No. 20. He stresses that the statements provided by Petitioner's friends were executed in June 2022, approximately twenty months post-vaccination. *Id.* Thus, he maintains they are "less reliable than contemporaneous medical reports." *Id.*

³ Petitioner's declaration is signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 2.

⁴ Although Petitioner's supplemental declaration is again signed under penalty of perjury as required by 28 U.S.C.A. § 1746 (Exhibit 10), the statements from her friends are unnotarized, and otherwise simply state that they understand the statement will be filed in Ms. Belker-Frechette's vaccine proceeding, without any express indicia of their veracity. Exhibits 11-12.

(citing *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed Cl 516, 523 (1993)). Along with his arguments regarding situs, Respondent maintains Petitioner has failed to provide sufficient evidence to establish that the onset or her pain occurred within 48 hours of vaccination and there is evidence that Petitioner had a history of prior left shoulder pain. *Id.* at 2-3.

The situs issue is now ripe for adjudication.

II. Issue

At issue is whether Petitioner received the October 5, 2020 flu vaccine in her left deltoid, as alleged.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), aff'd *per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); see also *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the finding regarding site of vaccination after a complete review of the record to include all medical records, affidavits, documentation, briefing, and additional evidence filed. Specifically, I base the finding on the following evidence:

- Approximately eleven months before receiving the 2020 flu vaccine alleged as causal (in late October 2019), Petitioner visited her current primary care provider (“PCP”), expressing a desire to discuss recent events and to obtain a “full baseline check.” Exhibit 1 at 15. It was noted that Petitioner “does not seek out medical care routinely” (*id.*), and the record indicates the visit was “to establish care” (*id.* at 18).
- During this PCP visit on October 23, 2019, Petitioner described a recent episode of mid-chest discomfort and mild numbness in her left arm (characterized as a chronic condition) after loading 600 pounds of corn into her truck. Exhibit 1 at 15. When listing her past symptoms over the last one to two years, she reported an earlier episode of chest discomfort, “intermittent neck pain, numbness of [her] upper left arm at times,” and itching in her right armpit. *Id.* The PCP assessed Petitioner as having noncardiac-related chest pain, prescribed medication for acid reflux, and administered a flu vaccine. *Id.* at 9 (list of immunizations), 9-13 (testing), 17-18 (PCP’s assessment and instructions).
- Approximately one year later – on October 5, 2020, Petitioner (then 62 years old) returned to her PCP clinic for administration of the flu vaccine alleged as causal. Exhibit 1 at 14; see *id.* at 9 (list of immunizations). The immunization record indicates Petitioner received the flu vaccine intramuscularly on October 5, 2020. *Id.* at 9. It does not indicate the site of vaccination. Similarly, no site of vaccination is provided for the other listed vaccination – the flu vaccine Petitioner received in 2019. *Id.*
- On November 13th, Petitioner returned to her PCP complaining of *left* shoulder pain and limited range of motion (“ROM”) which she attributed to the flu shot she received six weeks earlier.⁵ Exhibit 1 at 19. Reporting that she preferred to avoid medications, she described difficulty sleeping, lifting her arm overhead or behind her back, and one episode of left shoulder numbness. *Id.* Encouraging Petitioner to apply ice and heat and to take over the counter pain medication, the PCP prescribed topical gel and physical therapy (“PT”). *Id.* at 21.
- At her initial PT evaluation, Petitioner again reported left shoulder pain and limited ROM after receiving a flu vaccine on October 5, 2020. Exhibit 8 at 10-14. Characterizing the onset of her pain as “[s]udden” (*id.* at 9), she

⁵ Petitioner also described ongoing difficulties related to acid reflux. Exhibit 1 at 19-21.

described constant pain at an initial level of four and reduction to two out of ten after four weeks (*id.* at 7).

- After attending nine PT sessions through early January 2021, Petitioner was directed to return to her PCP for further diagnostic testing, due to her lack of progress. Exhibit 8 at 16-17.
- At her next PCP appointment (on January 5th), Petitioner reported continued left shoulder pain and a reluctance to use the prescribed gel due to a concern about its potential side effects. Exhibit 1 at 22. After Petitioner declined a steroid injection, the PCP referred her to an orthopedist and suggested acupuncture, if desired. *Id.* at 24.
- Petitioner attended one more PT session on January 7th. Exhibit 8 at 8. She was discharged on February 11th. *Id.*
- At her first acupuncture session on January 12th, Petitioner again reported left shoulder pain after receiving a flu vaccine three months earlier. Exhibit 3 at 1.
- By her fourth acupuncture session on January 22nd, Petitioner reported 50 percent improvement, even after shoveling snow. Exhibit 3 at 3. However, her pain had increased by her next session on January 24th, a change attributed to the use of a massage gun. *Id.* at 4.
- On March 10th, Petitioner began attending massage therapy. Exhibit 4 at 5. She again reported that her left shoulder pain was due to the vaccine she received, characterizing her injury as a “SIRVA – shoulder injury due to vaccine administration.” *Id.* at 6.
- During her next PCP appointment – held telephonically on March 24th, Petitioner reported “[s]ome improvement in ROM but no change in pain.” Exhibit 1 at 25. Noting that she had tried PT, Petitioner indicated she was attending acupuncture and had started massage therapy and yoga. She again declined a steroid injection, indicating she was “[t]errified of another injection.” *Id.* The PCP ordered an MRI and prescribed pain medication and a muscle relaxant. Exhibit 1 at 26-27.
- Performed on April 8th, the MRI revealed “mild tendinosis of the supraspinatus and subscapularis tendons, [n]o rotator cuff tear, . . . [g]lenohumeral joint capsulitis, . . . [m]ild tendinosis of the long head biceps

tendon, . . . [and] [m]ild degenerative arthrosis of the AC joint." Exhibit 1 at 7-8. There was "[n]o subacromial-subdeltoid bursal fluid" observed. *Id.* at 7. In the history portion of the MRI report, it is reported that Petitioner suffered "[s]houlder pain following vaccination fall 2020 [and] [l]imited range of motion." *Id.*

- Petitioner continued to attend acupuncture sessions throughout April, May, and early June 2021. Exhibit 5 at 3-22. She attended massage therapy until November 2021. Exhibit 6 at 4, 8-10.
- In her initial signed declaration, Petitioner described left shoulder pain onset immediately upon vaccination. Exhibit 2 at ¶ 8. She indicated that she believed the vaccine was given "much higher than any of [her] previous flu shots." *Id.*
- In her supplemental signed declaration, Petitioner maintains that the left shoulder pain she experienced after vaccination was different than her 2019 soreness. Exhibit 10 at ¶¶ 5-7, 9.
- In their signed statements, Petitioner's friends recalling observations and communications from Petitioner which support her claims of differing pain post-vaccination. Exhibits 11-12.

The above medical entries show that, when seeking treatment, Petitioner consistently identified her left shoulder as the problem, and attributed her pain to the flu vaccine she reported receiving in her left arm. She provided these histories, during the year following vaccination, to her PCP, physical therapist, acupuncturist, massage therapist, and the technician performing her April 2021 MRI. In both medical records and her first signed declaration, Petitioner described the flu vaccine as improperly administered – given too high in her left deltoid. Exhibit 1 at 19; Exhibit 2 at ¶ 8.

While originating from Petitioner, these statements are also set forth in contemporaneous records, and should therefore be afforded greater weight than any subsequent assertion or witness statement. The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this class of information, even when the record in question simply memorializes what the petitioner said at the time.

Although the vaccine record does not indicate the exact site of vaccination, it clearly establishes that, on October 5, 2020, Petitioner received an intramuscularly administered flu vaccine. Furthermore, the medical histories provided by Petitioner in the contemporaneously created medical records and supporting evidence from her PCP, other treaters, and friends provide persuasive evidence showing the vaccine was administered in Petitioner's left deltoid. And there is a dearth of evidence indicating that the vaccine was administered in any other location. I thus determine, based on the entire record, that Petitioner has provided preponderant evidence establishing that the flu vaccine to which Petitioner attributes her SIRVA was most likely administered in her left deltoid on October 5, 2020.

V. Scheduling Order

Based on recent data, I expect the HHS review to be completed in this case in May 2023. Although I have determined that Petitioner has provided sufficient evidence to establish that she received the flu vaccine in her left deltoid, as alleged, there is evidence showing she previously suffered chronic left arm numbness. And the results of the April 2021 MRI do not definitively show a SIRVA injury. These matters may require additional consideration.

On March 7, 2023, Petitioner forwarded a demand and supporting documentation to Respondent. ECF No. 21. Prior to the completion of the HHS review, she should make any needed adjustments to her demand and should file any updated medical records.

Petitioner's motion for a factual finding regarding the site of vaccination is GRANTED. Respondent shall file a status report indicating how he intends to proceed by no later than Tuesday, May 23, 2023. If interested in engaging in settlement or damages discussions, Respondent should provide an estimate of the amount of time needed to respond to Petitioner's demand.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master